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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,082	10/06/2003	Jacobus M. Lemmens	116.066	4414

7590 01/16/2007

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EXAMINER	
KRASS, FREDERICK F	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/678,082	LEMMENS ET AL.	
	Examiner	Art Unit	
	Frederick Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56 recites a composition which "has an added water content of 1.2 wt%". Since this is a single value, the later recitations of "0 to 1.0 wt%" and "0 to 0.8%" in claims 57 and 58, respectively, lack antecedent basis.

The examiner notes that this situation is apparently the result of a typographical error. The specification describes (page 8, lines 30 and 31) compositions having an added water content of "1.2 wt% or less"; apparently "or less" was omitted from the instant claim due to an inadvertent omission in drafting.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al (USP 6,113,944) in view of Benneker et al (USP 5,874,447) and Takado et al (USP 5,486,365).

The primary reference discloses paroxetine formulations for oral administration which are prepared by dry granulating in the absence of water. See column 1, lines 50-58 and column 2, lines 64-67. Conventional excipients used include calcium phosphate, sodium starch glycollate, and magnesium stearate. See column 2, lines 12-16. Working example 2 discloses a formulation comprising sodium starch glycollate, calcium

phosphate, and magnesium stearate; microcrystalline cellulose, lactose or any other diluent or excipient is not included therein. Dry granulation is taught to overcome the recognized problem of discoloration in which paroxetine takes on a pink hue (column 1, lines 35-47).

The primary reference differs from the instant claims insofar as it does not specify the use of sulfonate salts of paroxetine (it instead exemplifies the hydrochloride), nor does it specify the use of calcium hydrogen phosphate anhydrate (= anhydrous calcium hydrogen phosphate).

Benneker et al. (USP 5,874,447) teach that paroxetine sulfonate salts (such as paroxetine methane sulfonate) are preferable to paroxetine hydrochloride salts because the former do not undergo the discoloration associated with the latter when tabletted, and because the former have better water solubility (and thus better bioavailability). See column 1, lines 30-65. See also column 7, lines 8-13 (teaching that either wet or dry granulation may be used). Excipients are only generally taught.

Takado et al. (USP 5,486,365) teach that calcium hydrogen phosphate is an ideal excipient for pharmaceutical compositions because it provides excellent fluidity, increase stability, and decreases discoloration. See column 4, lines 10-23 and column 7, lines 43-46. The calcium hydrogen phosphate is preferably used in anhydrous form, the water content being minimized or eliminated by drying under heat (column 2, lines 29-34). Medicaments are only generally taught.

It would have been obvious to have used paroxetine sulfonates instead of hydrochlorides, and to have specifically used calcium hydrogen anhydrate instead of calcium phosphate generally, in formulating the pharmaceutical compositions of the

primary reference, motivated by the desire to further enhance discoloration resistance as taught by Benneker et al and Takado et al, respectively.

2) Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pathak et al (USP 6,113,944) in view of Benneker et al (USP 5,874,447) and Takado et al (USP 5,486,365).

The primary and secondary references, and the motivation for their combination, are discussed supra. The pharmaceutical compositions suggested by their combined teachings differ from the instant claims insofar as specific pH values are not provided.[1]

Generally, it is prima facie obvious to determine workable or optimal values within a prior art disclosure through the application of routine experimentation. *See* In re Aller, 105 USPQ 233, 235 (CCPA 1955); In re Boesch, 205 USPQ 215 (CCPA 1980); and In re Peterson, 315 F.3d 1325 (CA Fed 2003). Accordingly, it would have been obvious to have adjusted the relative percentages of the components suggested by the combined teachings of the primary and secondary references to arrive at those pH values providing optimal performance for a particular given pharmaceutical formulation, per the reasoning of the cited precedent.

[1] It will be presumed for the purposes of this rejection that claim 56 was intended to read "1.2 wt% or less", as discussed in the "Indefiniteness" section. (Moreover, Takado et al suggests the water content is a

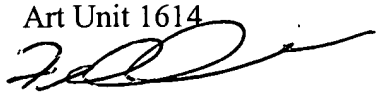
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached on Monday through Friday from 9:30AM to 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614



result effective variable, and thus variation in the residual water content would have been obvious in any case).